Meeting of the States Parties to the Conve[illegible] on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

19 July 2018

English only

2018 Meeting
Geneva, 4-7 December 2018

Meeting of Experts on Strengthening National Implementation
Geneva, 13 August 2018
Item 6 of the provisional agenda
Various ways to promote transparency and confidence building under the Convention

Building Confidence in Compliance: Peer Review Transparency Exercise at the Richard Lugar Center for Public Health Research (CPHR) of the National Center for Disease Control and Public Health (NCDC) in Tbilisi, Georgia

Submitted by Georgia, co-sponsored by Germany

I. Introduction

1. The success or failure of disarmament regimes depends on the actions of their respective States Parties, which need to cultivate these regimes and ensure their continued relevance in changing scientific and political contexts. Since the Fifth Review Conference in 2001, the Biological and Toxin Weapons Convention (BTWC) has seen three intersessional processes that have generated valuable ideas on possible steps to increase confidence in compliance, but have fallen short of more ambitious expectations. In this context, peer review activities, while neither a substitute for verification nor comparable with a compliance mechanism, may help boost confidence in States Parties' compliance with and commitment to the BTWC.

2. At the Seventh Review Conference in 2011, a working paper submitted by France proposed the idea of developing peer review activities "to provide for an assessment of the implementation of the Convention, thereby bolstering confidence among States Parties" [1]. Since then, the practical benefits of peer review activities in the context of the Convention

[1] BWC/CONF.VII/WP.28

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have been repeatedly explored, as 14 countries have hosted such exercises. They have also been presented in numerous additional working papers, such as the one submitted by Germany to the 2016 Eighth Review Conference and co-sponsored by 13 countries from all three regional groups.

3. The transparent demonstration of national implementation of the BTWC enhances confidence in compliance with the BTWC. The possibility of conducting on-site visits represents just one of various forms in which peer reviews can contribute to this objective. Yet, they serve as a connection between the theoretical discourse on implementation and concrete every-day procedures on BTWC-relevant sites. Following the German exercise in 2016 and the peer review exercise hosted by the Kingdom of Morocco in 2017, Georgia has therefore decided to host a similar visit at the Richard Lugar Center for Public Health Research (CPHR) of the National Center for Disease Control and Public Health (NCDC) in Tbilisi.

4. Like the previous exercises, this third on-site exercise, to which all States Parties to the BTWC will be invited, is intended to demonstrate that it is possible to reconcile a high level of transparency with the legitimate security and intellectual property interests of the visited facility. It is thus expected that it will represent a valuable contribution to the ongoing search for innovative and concrete ways to increase confidence in the implementation of the BTWC in the absence of a compliance mechanism.

II. The Peer Review Exercise at the NCDC Richard Lugar Center for Public Health Research

5. The Ministry of Foreign Affairs of Georgia has decided to carry out a peer review transparency exercise at the NCDC Richard Lugar Center for Public Health Research in Tbilisi, Georgia in order to strengthen confidence in compliance with the provisions of the BTWC. All interested States Parties to the BTWC are invited to apply for participation in this exercise planned for November 14 – 15, 2018.

6. The NCDC CPHR is a civilian facility working with BTWC-relevant pathogens and declared under the Confidence-Building Measures (CBM) submitted by Georgia. It is the first BSL3 laboratory established in the region as the result of the initiative of the US Senator Richard Lugar and serves both Georgia and the wider region. It offers detection and diagnostic capacities in regards to endemic and exotic diseases, like Dengue or Chikungunya, and is equipped to conduct bio-surveillance on natural foci – Tularemia, Anthrax and other zoonotic diseases.

7. Unfortunately, for capacity reasons, a maximum of 20 visitors can be accommodated. To ensure equal representation, these places will be filled with participants from all regional groups. Financial support for travel and accommodation will be provided upon request by the German Federal Foreign Office, thus ensuring a non-discriminatory approach. The only prerequisite stipulated in the invitation will be that participants must be willing to comply with the appropriate safety regulations for entering biological laboratories.

8. The visit will include a tour of the facility, a visit to the laboratories, conversations with staff in the laboratories, presentations and discussions of research activities, and an assessment meeting. For operational reasons, the visitors will be split into two teams of ten individuals each, which will both complete the same tour. The visit will be concluded by a closing session including further discussions, a summary, and a final assessment. The working language of the visit will be English.

9. All teams will be escorted on site and will be able to assess all aspects of the facility that are relevant to provisions of the BTWC and provided on the CBM form, comprising laboratory activities and equipment, infrastructure, security measures including access control, laboratory conduct, documentation in relation to research and development, including Dual Use Research of Concern (DURC), as well as procedures for the transfer and export of pathogens and toxins.

10. Exercise proceedings will allow for:

- examination of rooms, laboratory equipment and installations;
- requests for visual access to paper documents;
- requests for written answers to questions that were submitted in writing prior to the visit;
- interviewing of personnel;
- requests for photographs and the determination of geographical coordinates.

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Item 5 of the provisional agenda
Confidence Building Measures (CBM) submissions in terms of quantity and quality

Improving the Quality of CBM Information: A Review of Recent Proposals and Some Suggestions for Future Work

Submitted by the United States of America

Summary

CBMs should capture relevant, useful information in a clear and unambiguous way. Moderate changes to the existing CBM forms, including Forms "0", A (Part 2 (i)), Form E, and others would improve the saliency of information reported, thereby increasing the utility of CBMs as tools for generating discussion and preventing or reducing the occurrence of doubts or ambiguities. Given the limited time available in the formal Expert Meeting process, interested States Parties should consider convening open-ended, informal discussions with a view to developing a widely-supported package of proposals in time for the Ninth Review Conference.

I. Introduction

1. Achieving the underlying purpose of the BWC Confidence-Building Measures requires not only increasing the number of submissions, but improving the quality and relevance of the information provided. While the Seventh Review Conference adopted a number of minor amendments, the CBMs are nevertheless largely unchanged since the Third RevCon in 1991. Recent efforts to increase submission of CBMs – including facilitation through the eCBM tool – are important steps toward strengthening this tool.

Concurrently, updating the CBM forms to capture more timely and relevant information would improve their utility as a vehicle for improving confidence in compliance and transparency amongst States Parties. As the United States of America has previously noted, States Parties should consider "how to make the data they [CBMs] contain more readily accessible and how to encourage States Parties to make constructive use of them. Without these steps, submission of CBMs – even on a universal basis – will be a hollow, ceremonial accomplishment, and do little to achieve the goals for which the CBMs were created."[1]

2. At the 2017 Meeting of States Parties, Parties agreed to a Meeting of Experts on "strengthening national implementation," which as a part of the 2018-2020 intersessional period, includes consideration of "CBM submissions in terms of quantity and quality". With the goal of improving the quality of CBMs in mind, this paper amalgamates select aspects of the numerous thoughtful proposals put forward by States Parties, with the hopes of generating renewed, vigorous discussion, including new proposals.

New Proposal: Make the CBM Cover Sheet ("Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange") User-Friendly

3. The CBM Cover Sheet, or Form "0", is often the only CBM a State Party submits. For States Parties completing CBMs for the first time, it is their introduction to the process. Although it is simple to fill out, it is not at all simple to understand. At present, this form consists of the short title of each CBM form, with a set of check boxes [Figure 1 below]. The Cover Sheet lacks even basic information as to what each CBM form contains—so to use this "simple" form, a State Party's representative must first familiarize him- or herself with the entire set of CBM forms. This may well act as a disincentive to States Parties' submitting CBMs for the first time—and may also increase the chances that a submission consisting only of "form 0" may, in fact, be in error. Without making any changes at all in the information States Parties are requested to report, it would be possible to add to form 0 very brief descriptions of each form to help States Parties easily determine which forms are relevant for them and require further attention. Descriptions could be short, specific and adapted from existing CBM form language. For example, for CBM Form A (Part 2), a description could be as follows: "This form asks States Parties to complete information about those research facilities they maintain that conduct research with highly pathogenic or virulent biological agents. Such facilities are often informally called 'high-containment'. For Form E, "This form asks about national laws, regulations, or other measures you have adopted in order to implement the Convention."

[1] BWC/MSP/2012/MX/WP.4

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1	☐	☐	☐
A, part 2 (i)	☐	☐	☐
A, part 2 (ii)	☐	☐	☐
A, part 2 (iii)	☐	☐	☐
B	☐	☐	☐
C	☐	☐	☐
E	☐	☐	☐
F	☐	☐	☐
G	☐	☐	☐

Figure 1: Snapshot of blank 2018 CBM Form "0" – a model of clarity?

CBM Form A (Part 2 (i)): "Exchanges of information on national biological defence research and development programmes"

5. Form A (Part 2 (i)) calls upon States Parties to describe the nature and extent of their respective biodefense research apparatuses. In the United States' 2016 paper, "Strengthening confidence-building and consultative mechanisms under the Biological Weapons Convention" (BWC/CONF.VIII/PC/WP.6), we proposed clarifying that "national biodefense programs" includes both civilian and military biodefense efforts. The paper notes that approximately a third of States Parties report biodefense research activities undertaken within their civilian sectors and that, for "the remaining two-thirds of States Parties, it is not clear whether they have construed the request for information to apply only to military programmes, or whether they do not have biodefense research programs conducted by civilians aimed at protecting the civilian population."

6. We continue to advocate for these changes to Form A (Part 2 (i)). While comprehensive reporting on military programmes remains of vital importance, many States Parties do not maintain extensive military biodefense research apparatuses. However, many States Parties do concentrate or co-locate their biodefense research within their civilian sectors – to include their public health institutions. The ambiguity with regard to the scope of reporting intended under "national biodefense programmes" may reduce the incentive of such states to report in this form. Clarifying the scope of Form A (Part 2 (i)), thereby capturing this potentially large swath of civilian biodefense research, will support increased transparency amongst States Parties regarding biodefense, including better insight into potential dual-use activities. It will, in any case, provide greater clarity concerning what is being declared, and thus reduce any perceived need for consultations.

CBM Form E, "Declaration of legislature, regulations, and other measures"

7. The United States also proposes a modest modification to CBM Form E reporting by requesting short descriptions of States Parties implementation measures. Like "Form 0", the current Form E consists of simple check-boxes, with no opportunity for States Parties to provide supporting or clarifying information. Adding such information would enable States Parties to better understand the nature and extent of one another's implementation; such information could also serve as illustrative examples or guidance for States Parties seeking to develop their own implementing legislation, regulation, or other measures. Short descriptions within each category of Form E could therefore provide the dual benefit of reinforcing transparency and confidence in compliance and serving as a potential resource for States Parties in their national implementation. As the United States noted in 2016, "[s]uch national implementation measures are fundamental steps to upholding and strengthening the norm against the misuse of biological materials, and critical to guarding against the acquisition and use of biological weapons by both State and non-State actors"; strengthening existing tools for national implementation therefore remains of paramount importance. [2] The United States currently provides such descriptions, on a voluntary basis, immediately following the official Form E.

8. In its 2016 paper, "Strengthening confidence-building measures in regard to dual use materials" (BWC/CONF.VIII/PC/WP.35), Germany proposed expanding Form E to address the potential dual-use risk of exporting "genetically modified organisms and synthesised genetic sequences" (Figure 2 below). With this proposal, Germany noted its desire to update the CBMs to better reflect information on "additional risks originating from developments in the field of genetic engineering of microorganisms and the resulting availability of synthetic DNA." As stated above, the United States of America recommends that any expansion of Form E also include a short description of the nature of associated legislation or regulation.

Form E

Declaration of legislation, regulations and other measures Relating to	*Legislation*	*Regulations*	*Other measures*	*Amended since last year*
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes/No	Yes/No	Yes/No	
(b) Exports of micro-organisms and toxins	Yes/No	Yes/No	Yes/No	
(c) Imports of micro-organisms3 and toxins	Yes/No	Yes/No	Yes/No	
(d) Biosafety and biosecurity	Yes/No	Yes/No	Yes/No	

[2] BWC/CONF.VIII/PC/WP.6

Declaration of legislation, regulations and other measures Relating to	*Legislation*	*Regulations*	*Other measures*	*Amended since last year*
(e) Exports of genetic elements or genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms addressed under (b) or coding for any of the toxins addressed under (b), or for their sub-units	Yes/No	Yes/No	Yes/No	

Figure 2: Germany's proposed modification to CBM Form E

CBM Form G, "Declaration of vaccine production facilities"

9. The Netherlands, Switzerland and the United Kingdom of Great Britain and Northern Ireland's 2017 paper notes a potential ambiguity associated with existing Form G reporting. [3] In addition, the Russian Federation's proposal to supplement "Form G's information on human vaccine production facilities with similar data on animal vaccine production facilities," which was included in its 2016 paper "Proposal to enhance the format of confidence-building measures under the Biological Weapons Convention" is also of potential interest. [4] The United States appreciates Russia's willingness to engage in important discussions to strengthen the CBMs.

Addition to Form G: Declaration of vaccine production facilities

Add part II as follows:

State Party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of animals.

Declaration of vaccine production facilities for the protection of animals:

(a) Name of facility.

(b) Location (mailing address).

(c) General description of the types of diseases covered.

Figure 3: Russia's proposed modification to CBM Form G

II. Conclusion and Recommendations

10. CBMs remain an important political commitment for all States Parties. As the pace of development in science and technology continues to be rapid, States Parties have an important responsibility to ensure that the tools available to bolster the Convention and maintain its relevance are concurrently strengthened. Steps can be taken throughout the intersessional period to support substantive work on CBMs:

[3] BWC/MSP/2017/WP.6

[4] BWC/CONF.VIII/WP.9

- The ISU should develop an annotated version of Form 0, providing brief explanations of what each form entails, for consideration by States Parties at the 2018 MSP.
- Interested States Parties should be encouraged to organize informal meetings to discuss the proposals of this paper, and any new proposals put forward by States parties, with a view to developing recommendations that would command broad support.
- To achieve such support, and taking into consideration the lack of agreement on more sweeping proposals for CBM reform, States Parties should focus primarily on refinements to the existing CBMs, to clarify reporting requirements or add detail, rather than new CBMs or major expansions, and should be mindful of avoiding significant increases in reporting burden.
- All such work should be conducted transparently, open to all interested SPs, and in consultation with the MX 3 Chair.
- Throughout the remaining intersessional period, States Parties should continue to encourage development and debuting of the CBM e-tool by the ISU, and welcome its use, on a voluntary basis, by States Parties.

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Meeting of Experts on Strengthening National Implementation
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Item 4 of the provisional agenda
Measures related to Article IV of the Convention

Strengthening national implementation: The UK Biological Security Strategy 2018

Submitted by the United Kingdom of Great Britain and Northern Ireland

I. Introduction

1. On 30 July 2018, the UK published an overarching national biological security strategy. This brings together, and sets out in one place for the first time, the wide range of activity carried out across government departments and agencies to protect UK citizens and British interests from the risk of a significant infectious disease outbreak, no matter the source – natural, deliberate or accidental. The strategy also explains how in the future the UK will coordinate its activity more strongly and take a truly comprehensive approach to meet the evolving risks (and opportunities) in this area. This will mean closer work between government departments, so that prevention activity, the deployment of response capabilities, research programmes, and our engagement with international partners, industry and academia align and their impact is maximised. This Working Paper provides a brief summary of the strategy's key themes.

II. Strategy: a summary

2. The strategy draws together the work that takes place across the UK Government to protect the UK and its interests from significant biological risks, no matter how these occur and no matter who or what they affect. It reflects on the evolving landscape and sets out how the UK will build on its existing activity to improve further its ability to reduce and respond to risks, and to exploit opportunities to address such risks.

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3. The first part of the strategy sets out the broad strategic context; it describes the nature of the biological risks and the opportunities for addressing them, and looks at how this landscape is continuing to evolve. It notes that, while the likelihood of many of the worst-case biological risks is low (particularly those that describe accidental releases or deliberate attacks), their potential impact is significant. Factors such as globalisation and developing technology all affect the risk assessment – bringing both challenges and opportunities.

4. The second part sets out that the UK's response to this context rests on four key pillars:

- **Understand** the biological risks that we face today and could face in the future.
- **Prevent** biological risks from emerging (where possible) or from threatening the UK and UK interests.
- **Detect**, characterise and report biological risks when they do emerge, as early and reliably as possible.
- **Respond** to biological risks that have reached the UK or UK interests, to lessen their impact and allow the rapid return to business as usual.

5. Two themes run through all four pillars:

- All elements of the Government's response must be underpinned by the right scientific capabilities and capacity, now and in the future.
- The UK must be able to take advantage of the opportunities that the biological sector offers, as well as responding to the risks.

III. Strategy Implementation

6. Governance for much of the activity described in the UK's new strategy falls within government departments' existing portfolios and governance mechanisms. However, the strategy outlines commitments that will only be met if the Government works together across the diverse range of departments and agencies involved. A senior cross-Government governance board will be responsible for these commitments (as well as any new areas of work or identified gaps that emerge through implementation of the strategy). This governance board will report to the National Security Council through the Home Office Security Minister. The Government Chief Scientific Adviser will maintain an oversight of developments under the strategy.

IV. Relevance for the BTWC and MX process

7. Many aspects of the UK strategy and its implementation in the years ahead may help inform discussion of the agenda items of the Meetings of Experts in the current intersessional programme. Actions already underway or planned give effect to the object and purpose of the BTWC itself. Examples include, but are certainly not limited to the following topics:

(a) Preventing biological risks includes building healthcare capacity and biological security in vulnerable regions of the world – **MX 1, MX 2** and **MX 3**;

(b) Improving laboratory capacity for diagnosis as well as surveillance of antimicrobial resistance (AMR, which can lead to drug-resistant infections in both humans and animals) in low and middle income countries through the £265 million commitment of the Fleming Fund. Building up national capability to detect and track trends in AMR in

human and animal health, as well as in agriculture, will enable countries, regions and global actors to tackle AMR – **MX 1 and MX 2**;

(c) Science and technology run through every element of our response to significant biological risks – from understanding the nature of the risks to responding to events that we are unable to prevent, everything government does must be underpinned by high quality science and evidence if it is to be effective. Accessing this science and advice involves the critical scientific capabilities within government, as well as working very closely with industry, academia and international partners, such as those contributing to **MX 2**.

(d) Supporting the development of new diagnostics, drugs, vaccines and other products that are effective, affordable, can be stored without the need for refrigeration, will shorten or simplify existing treatment schedules to reduce the risk of inappropriate use (which can cause AMR), and can be delivered without the need for highly trained staff. This will include work as part of the Ross Fund portfolio[1], to support research to develop new diagnostics and drugs to control neglected tropical diseases and strengthen the implementation of disease control programmes. Such activities are relevant for **MX 1** and **MX 4**.

(e) Working with governments and international organisations, and with industry and academia to ensure that we have in place within the UK education and training promoting a responsible life sciences research culture, and to contribute to improving education and training on these issues overseas – **MX 2** and **MX 3**.

(f) Ensuring responsible access to and work with hazardous biological materials and expertise (both in the UK and overseas) – **MX 3**.

(g) Making full use of the UK Public Health Rapid Support Team[2] – established in 2016 as a full-time deployable team of multidisciplinary public health experts. The team can deploy within 48 hours to support low- and middle-income countries to investigate and respond to disease outbreaks that pose a global threat, before they have the chance of become a global health emergency – **MX 4**.

(h) Being able to intervene rapidly (including as part of the global community) to stop outbreaks of diseases with pandemic potential at source – **MX 4**.

(i) Continuing to support the International Animal Health Emergency Reserve agreement signed between the UK, Ireland, USA, Canada, Australia and New Zealand to provide veterinary and technical staff in the event of an outbreak of animal disease – **MX 4**.

8. The UK is globally renowned for the quality of our preparedness planning, and we have world-leading capabilities to address significant biological risks. Across local and national Government (including the devolved administrations) and through our work internationally, the UK invests hundreds of millions of pounds a year in protecting against and preparing for disease outbreaks and biological incidents. Much of this, if not all of it, is directly or indirectly relevant for the BTWC's object and purpose.

9. A copy of the UK's biological security strategy is at the Home Office website: https://www.gov.uk/government/publications/biological-security-strategy.

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[1] See BWC/MSP/2017/WP.7, United Kingdom, Report on implementation of Article X of the Biological and Toxin Weapons Convention paragraph 2 and 3 for more detail on The Ross Fund.

[2] See BWC/MSP/2018/MX.4/WP.2 for more detail.